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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,214	10/01/2003	Herman Berg	1110-2	9643

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/677,214	Applicant(s) BERG ET AL.	
	Examiner Catherine S. Williams	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 27, 28 and 30-41 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 12, 20-24 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 11, 13-19, 27, 28, 30-33 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

- a) Electric pulse with light,
- b) Electric pulse with light and visualizing agent,
- c) Heat with light,
- d) Heat with light and visualizing agent, and
- e) Electric pulse with light, heat and visualizing agent.

This application contains claims directed to the following patentably distinct sub-species of the light application:

- a) Extracorporeal, and
- b) Internally.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is considered generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Daniel Chambers on 11/03/05 a provisional election was made with traverse to prosecute the invention of species a, the electric pulse with light, claims 1-6,10-11,13-19,25-33,35-41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-9,12,20-24 and 34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6,13-14,17-18,32-33, 36-39 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Walker et al (6,041,252). Walker discloses a drug delivery system that includes a method for drug delivery to a specific target in the human body combined with photodynamic therapy. The method teaches providing a photooxidizing agent, applying an electric pulse to electroporate a cell with the photooxidizing agent, and applying in combination a light (laser conductor) to the cell (after electroporation). See 3:16-21 and 38:26-36. Multiple electric pulses are applied (7:16) by a plurality of electrodes (8:3). See also 7:4+ for amplitude and duration. The wavelength of the light is 630nm (see 38:33). The reference also teaches a method of heating the cell. See 39:55+. The photooxidizing agent can be hematoporphyrin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-28,30 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. Walker meets the claim limitations as described above but fails to include a cytostatic agent specifically daunomycin, adriamycin, actinomycin or 1 aevuline acid and treating histiocytic cancer.

At the time of the invention, it would have been obvious to substitute any of the above cytostatic agents for the hematoporphyrin of Walker or use the device of Walker to treat histiocytic cancer. Applicant has not disclosed that these agents versus other cytostatic or photosensitive agents or treating histiocytic cancer provides an advantage, solves a problem, or is used for a particular purpose. Any of the above cytostatic agents would equally perform the same function, therefore the substitution would have been proper. Additionally, the motivation for the incorporation would have been in order to utilize a readily available agent in the method or treat another cancer with the procedure.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. Walker meets the claim limitations as described above but fails to include a meander electrodes. At the time of the invention, it would have been obvious to substitute meander electrodes into the invention of Walker. Applicant has not disclosed that meander electrodes versus other electrodes provides an advantage, solves a problem, or is used for a particular purpose. The meander electrodes would equally perform the same function, therefore the substitution would have been proper. Additionally, the motivation for the incorporation would have been in order to utilize a readily available electrode in the method.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Mir et al (US Pat# 5,674,267). Walker meets the claim limitations as described above but fails to include using at least two needle electrodes.

Mir teaches the use of multiple needle electrodes and electric pulses for aiding the transport of an agent into biological tissues. The needles are made of metal and therefore are heatable.

At the time of the invention, it would have been obvious to incorporate the needle electrodes into the invention of Walker as a device for carrying out the electroporation method as disclosed. Both references are analogous in the art of electroporation systems; therefore, a combination is proper. Additionally, the needles of Mir are designed for the same function as disclosed by Walker and would have been incorporated by one skilled in the art to carry out the disclosed functioning of the system.

Claims 15-16 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Kennedy et al (US Pat# 5,079,262). Walker meets the claim limitations as described above but fails to include using a tungsten lamp or protoporphyrin IX.

However, Kennedy discloses a method of photodynamic therapy that includes using a tungsten lamp and protoporphyrin IX. At the time of the invention, it would have been obvious to substitute the tungsten lamp of Kennedy for the laser and agent of Walker. Both methods are analogous in the art and therefore a combination is proper. Additionally, the tungsten lamp and protoporphyrin IX of Kennedy would perform the same function just as well as that disclosed by

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Walker. The motivation for the incorporation would have been in order to use a readily available agent and light source in the method.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al in view of Meserol et al (US Pat# 5,474,528). Walker meets the claim limitations as described above but fails to include an extracorporeal light application.

Meserol teaches the use of a patch for applying light to the exterior surface of the body. Both references are analogous in the art of photodynamic therapy systems; therefore, a combination is proper. Additionally, the patch of Meserol is designed for the same function as disclosed by Walker, i.e. application of light to biological tissues and would have been incorporated by one skilled in the art to carry out the disclosed functioning of the system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams

November 28, 2005